neoBLUE® mini
LED Phototherapy

User Manual

natus®

Caution: Federal Law (U.S.) restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).

Natus is a registered trademark of Natus Medical Incorporated

neoBLUE mini is a trademark of Natus Medical Inc.

Biliband is a trademark of Nascor Pty, Ltd

BiliBlanket is a registered trademark of Ohmeda.

Bili-Meter is a trademark of Olympic Medical.

© 2006 Natus Medical Inc. All rights reserved.

This manual may not be reprinted or copied in whole or in part without written consent from Natus Medical Inc. The content of this manual may change without notice.

Natus Medical Inc.
1501 Industrial Road
San Carlos, CA 94070 USA
Telephone +1 650 802 0400
Fax +1 650 802 0401

Technical Service +1 888 496 2887
Technical Service Fax +1 650 802 8680
E-mail: technical_service@natus.com
Customer Service +1 888 622 2427
Customer Service Fax +1 650 802 6620
E-mail: customer_service@natus.com

International Support - Please contact your local Distributor.
Distributor locations can be found at www.natus.com

EU Representative
Fischer-Zoth Diagnosesysteme GmbH
Walter-Kolbenhoff-Str. 34
D-82110 Germering
Germany

CE 0197

Contents

1 Product Description

- **1.1 Intended Use**
- **1.2 Physical Characteristics**
- **1.3 Light Source**
- **1.4 Adjustable Arm**
- **1.5 Power Requirements and Accessories**
- **1.6 Accessory Pack**

2 Safety Information

- **2.1 Explanation of Terminology**
- **2.2 General Safety Information**
- **2.3 Safety Symbols**

3 Components and User Controls

- **3.1 Components**
- **3.2 User Controls**

4 Assembly and Operating Instructions

- **4.1 Setting Up the Device**
- **4.2 Preparing Infant for Phototherapy**
- **4.3 Administering Phototherapy**

5 Troubleshooting Guide

6 Routine Cleaning & Maintenance

- **6.1 Checking the Light Intensity**
- **6.2 Adjusting the Light Intensity**
- **6.3 Cleaning**

7 Technical Reference

8 Specifications

9 Measuring the neoBLUE mini Light with a Photometer

1 Product Description

The neoBLUE®mini LED Phototherapy System consists of two components – the neoBLUE mini phototherapy light source and the adjustable arm with pole mount.

1.1 Intended Use

The neoBLUE mini LED Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia. The light can be used for infants in an open bed, incubator, bassinet, or radiant warmer.

Important! *Before administering phototherapy with the neoBLUE mini light, read all sections of this manual carefully. There are safety considerations that should be read and understood before use.*

1.2 Physical Characteristics

The neoBLUE mini device is a mobile phototherapy light that delivers a narrow band of high-intensity blue light via light emitting diodes (LEDs) to provide treatment for neonatal hyperbilirubinemia.

1.3 Light Source

The light is housed in a lightweight plastic enclosure. When used with the arm, the light can be positioned in multiple positions and used with a variety of patient enclosures such as open beds, incubators, bassinets, or radiant warmers.

The light output is optimized to provide a peak intensity of 30-35 $\mu W/cm^2/nm$. Blue LEDs emit light in the range of 400 – 550 nm (peak wavelength 450-470 nm). This range corresponds to the spectral absorption of light by bilirubin, and is thus considered to be the most effective for the degradation of bilirubin. Blue LEDs do not emit significant energy in the ultraviolet (UV) or the infrared (IR) region of the spectrum, so there is no concern about UV or IR exposure to or excessive warming of the infant. As with all phototherapy lights, protective eyeshades must be used to protect the infant's eyes from excessive light exposure.

⚠ ***Warning! Eye Protection:*** *Do not look directly into the LEDs. During treatment, always protect the baby's eyes with eye patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye patches or equivalent.*

LEDs have minimal light output degradation over their lifetime with proper use. Nevertheless, the user can adjust the output of the LEDs using the potentiometer located on the side of the light enclosure. The light is expected to operate as specified for at least 3,000 hours.

1.4 Adjustable Arm

The arm is designed to attach to poles with 0.75 to 1.5 inch (1.91 to 3.81 cm) diameters.

1.5 Power Requirements and Accessories

The light runs off a 12V DC power supply. The power supply is mains-power operated. The power unit is supplied pre-attached to the pole mount portion of the arm. Grooves in the bottom of the arm hold the power cord for safe cable management.

1.6 Accessory Pack

An accessory pack is included with each light. The accessory pack contains the following items: a CD containing the user manual and service manual and a power cord.

2. Safety Information

2.1 Explanation of Terminology

This manual presents three types of precautionary information. The three types of statements carry equal weight; that is, they are of equal importance to the safe and effective use of the light. Each statement is categorized by using an introductory word in boldface as follows:

⚠ ***Warning!*** *Identifies conditions or practices that might present danger or possible injury to the patient and/or user.*

Important! *An instruction provided to help ensure correct clinical results and provide quality assurance to the phototherapy procedures.*

Caution: *An instruction that, if not followed, can result in a condition that could damage the light.*

Other explanatory information is highlighted with the word ***Note***. Information in this category is not considered precautionary.

Note: *Background information provided to clarify a particular step or procedure.*

2.2 General Safety Information

Before administering phototherapy, read all sections of this manual carefully. Observe all precautions to ensure the safety of the patient and those near the instrument. In addition, please refer to your hospital policy and procedure for phototherapy administration.

⚠ ***Warning!*** *Incorrect use of the light, or the use of parts and accessories that are not manufactured or supplied by Natus Medical Inc., can damage the light, and may cause injury to the patient and/or user.*

Do not use the light if any parts appear damaged or if there is any reason to believe that it is not functioning properly. Contact Natus Medical Technical Service or your authorized service provider.

⚠ ***Warning! Attachment of Arm with Pole Mount:*** *When attaching the light to any floor standing pole, the user must validate that EN 60601-1/UL2601-1 standards for stability in normal use is met.*

⚠ ***Warning! Attachment of Arm with Pole Mount:*** *Ensure that the pole mount is properly seated around the pole prior to use to prevent slippage during use. Ensure that all screws and bolts are secure prior to use.*

⚠ ***Warning! Weight Limitations of Arm:*** *The arm has been validated to hold the weight of the light enclosure only. Do not hang anything from the arm or power cord.*

⚠ ***Warning! Arm Adjustments:*** *The arm folds into itself for optimal space utilization. Use care when repositioning the arm to prevent pinching yourself.*

⚠ ***Warning! Eye Protection:*** *Do not look directly into the LEDs. During treatment, always protect the baby's eyes with eye patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye patches or equivalent.*

⚠ ***Warning! Skin Temperature:*** *The use of skin-controlled mode of the incubator or radiant warmer is recommended. In addition, use of reflective foils may cause hazardous body temperatures. Monitor the infant's skin temperature per your hospital policy during phototherapy to avoid fluctuations in body temperature.*

⚠ ***Warning! Heat Supply:*** *The phototherapy light may impact the heat supply in thermotherapy devices (incubators, radiant warmers, or heated mattresses) and the patient's body temperature.*

⚠ ***Warning! Use with Radiant Warmers:*** *Do not place the phototherapy light directly under radiant heat sources. The light should be placed up to 12 inches (30.5 cm) from the infant, in line with the side of the heat element and angled toward the infant.*

⚠ ***Warning! Ambient Conditions:*** *Varying ambient conditions, such as the ambient temperature and/or different radiation sources, may adversely affect the patient. Please refer to your hospital phototherapy policy and procedure regarding appropriate ambient conditions.*

⚠ ***Warning! Operator Safety:*** *Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the illuminated area. Using the neoBLUE mini device in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects. Guard Dog Bones glasses (p/n 413BB) are recommended and are available online at www.safetyglasses.com or via phone at 1-800-870-6189 (US Only).*

⚠ ***Warning! Photoisomers:*** *Bilirubin Photoisomers may cause toxic effects.*

⚠ ***Warning! Clear Lens:*** *Do not use the light if the lens is missing or damaged. The lens is a plastic shield that provides electrical safety by protecting the baby, operator and the unit from incidental debris or fluids.*

⚠ ***Warning! Photosensitive Drugs:*** *The light generated can degrade photosensitive medications. Do not place or store any drugs near or in the illuminated area.*

⚠ ***Warning! Combustible Gases:*** *Do not use the light in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anesthetic agents).*

⚠ ***Warning! Disconnect Electrical Power:*** *Always switch off the power and disconnect the power cord when cleaning the light.*

Important! Use of Nonstandard Components: *The unit uses a specific type of LED. Consult the manufacturer for repair and replacement of LEDs. Use of incorrect LEDs can adversely affect performance and/or damage the light.*

2.3 Safety Symbols

⚠ ***Warning!*** *Be aware of the following symbols, which appear on the device.*

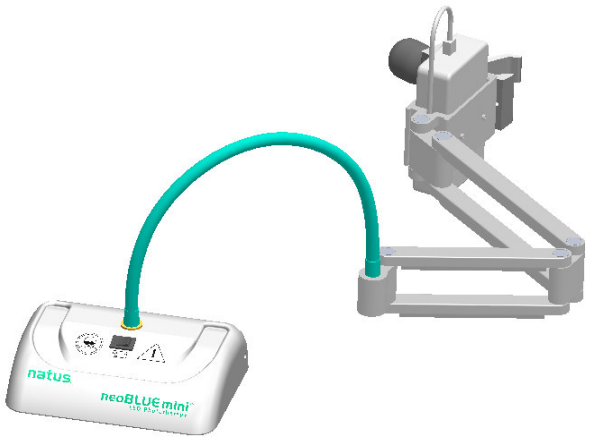
Symbol	Meaning
	Type BF rated for patient-applied parts
	Double-insulated (Class II)
	On (mains power on)
	Off (stand-by)
	Attention, consult product documentation
	Always protect the baby's eyes with eye patches or equivalent
EC REP	Authorized European Representative
XXXX	Manufacture Date

Natus	Manufacturer
	WEEE Directive (Waste from Electrical and Electronic Equipment Directive) Symbol – Product should not be disposed of in normal waste

3. Components and User Controls

3.1 Components

The neoBLUE mini phototherapy system includes the components shown in the following figure.



Main Device Components

Light Enclosure: The light enclosure can be tilted by grasping the device and/or gooseneck. Gross movements should be made with the arm while finer adjustments can be made with the light enclosure and gooseneck. The light enclosure swivels around the gooseneck to facilitate proper targeting.

Clear Lens: The lens is a plastic shield that provides electrical safety by protecting the baby and the unit from incidental debris or fluids.

Arm: The adjustable arm allows positioning of the light in multiple locations and angles. The arm is adjustable in five locations. A hex wrench is required. The light can be positioned vertically by moving it up and down the pole.

Note: *The optimal position for the arm is parallel to the desired light height.*

Vents: There are multiple vents at the back of the light enclosure.

Caution: *To avoid overheating the light, do not cover vents.*

3.2 User Controls

On/Off Switch: Use this switch to turn the light ON (|) or OFF (⏻). The switch is located on the top of the light enclosure.

Potentiometer: The potentiometer is used to adjust the light intensity as necessary. *(See Service Manual for more details)*

4. Assembly and Operating Instructions

4.1 Setting Up the Device

1. **Attach the arm** only to the manufacturer's specified location on the radiant warmer or incubator. If an open bed or bassinet is being used, attach the arm to a free-standing pole that meets the requirements for safety listed below. Attach the power cord to the power supply and plug into AC outlet.

   ⚠ ***Warning! Attachment of Arm with Pole Mount:*** *When attaching the light to any floor standing pole, the user must validate that EN 60601-1/UL2601-1 standards for stability in normal use is met.*

   ⚠ ***Warning! Attachment of Arm with Pole Mount:*** *Ensure that the pole mount is properly seated around pole prior to use to prevent slippage during use. Ensure that all screws and bolts are secure prior to use.*

   ⚠ ***Warning! Weight Limitations of Arm:*** *The arm has been validated to hold the weight of the light enclosure only. Do not hang anything from the arm or power cord.*

   ⚠ ***Warning! Arm Adjustments:*** *The arm folds into itself for optimal space utilization. Use care when repositioning the arm to prevent pinching yourself.*

2. **Check intensity.** Before use, check the intensity of the light using a spectrophotometer per your institution's procedures (see Section 6.1, "Checking the Light Intensity"). The light has been calibrated with the Ohmeda BiliBlanket® Meter II to deliver a peak intensity of 30-35 $\mu W/cm^2/nm$ at a 12 inch (30.5 cm) distance from the baby. Please refer to section 9 of this manual or Tech Note, P/N 051124 for information on other meters.

4.2 Preparing Infant for Phototherapy

1. **Prepare infant.** The infant may lie in an open bed, incubator, bassinet, or radiant warmer.

   ⚠ ***Warning!*** *Select only infants for whom phototherapy has been prescribed.*

2. **Shield infant's eyes** with protective eye shields, such as Biliband™ Eye Protectors, designed for use during phototherapy.

   ⚠ ***Warning! Eye Protection:*** *Do not look directly into the LEDs. During treatment, always protect the baby's eyes with eye patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection.*

3. **Position light over infant.** Position the face of the light enclosure towards the infant. The light enclosure can be tilted by grasping the device and/or gooseneck. Gross movements should be made with the arm while finer adjustments can be made with the light enclosure and gooseneck. The light enclosure swivels around the gooseneck to facilitate proper targeting.

The adjustable arm allows positioning of the light in multiple positions. The arm is adjustable in five locations. The light can be positioned vertically by moving it along the pole.

The following table outlines the changes in surface area and intensity based on distance from the light to the infant. The light has been calibrated with the Ohmeda BiliBlanket® Meter II to deliver a peak intensity of 30-35 µW/cm^2/nm at a 12 inch (30.5 cm) distance from the baby. Please refer to section 9 of this manual or Tech Note, PN 051124 for information on other meters.

The light intensity can be adjusted with the potentiometer during routine service/maintenance.

Distance from Infant	Peak Intensity	Surface Area
8 inches (20.3 cm)	37-40 µW/cm^2/nm	35 square inches (225.8 cm²) Approximately 5" x 7" (12.7 cm x 17.8 cm)
12 inches (30.5 cm)	30-35 µW/cm^2/nm	40 square inches (258.1 cm²) Approximately 5" x 8" (12.7 cm x 20.3 cm)
18 inches (45.7 cm)	22-25 µW/cm^2/nm	48 square inches (309.7 cm²) Approximately 6" x 8" (15.2 cm x 20.3 cm)

4.3 Administering Phototherapy

1. **Switch on power,** using the power switch.

⚠ ***Warning! Operator Safety:*** *Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the illuminated area. Using the neoBLUE mini device in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects. Guard Dog Bones glasses (p/n 413BB) are recommended and are available online at www.safetyglasses.com or via phone at 1-800-870-6189 (US Only).*

2. **Monitor the patient** during treatment.

⚠ ***Warning!*** *Regular monitoring during treatment is recommended. Use the following guidelines:*

- *Measure the patient's bilirubin level periodically during treatment per your institution's procedures.*
- *Turn off the light when checking the baby's condition and assessing skin color.*
- *Follow standard procedures for monitoring patient temperature and fluid status.*
- *Verify that the baby's eyes are protected and free of infection per your institution's procedures.*

3. **When finished**, switch the power off and remove the light from the therapy area.

5. Troubleshooting Guide

Note: neoBLUE mini device Service Manual available separately. In the USA, contact Natus Technical Service at +1 (888)-496-2887 or E-mail: technical_service@natus.com. International Support - Please contact your local Distributor. Distributor locations can be found at www.natus.com

⚠ ***Warning!*** *Disconnect power cord before opening the light for repair.*

Symptom	Probable Cause	Corrective Action
Light does not appear when device is turned on	No power	Verify that the AC outlet is functioning.
	Power switch not in correct position	Ensure that the power switch is in ON (|) position
	Power cord not plugged in all the way; or is defective	Check to make sure that the power cord is plugged in all the way to the device socket. If the device will still not turn on try another power cord.
Lens has become excessively hot (above 50°C/122°F)	Fan not working	Verify that vents are not blocked. If the lens surface has become hotter than 50°C (122°F), verify that the fan is functioning correctly.
Baby becomes too warm	Fan not working	Verify that vents are not blocked. If the baby becomes too warm, verify that the fan is functioning correctly.
Enclosure bubbles or starts to deform	Light too close to radiant heat source	Reposition the light to the side of radiant warmer - no farther than 12 inches (30.5 cm) from the infant.
LED string(s) goes out	LED short or open	Increase the intensity if necessary. If the device still produces enough light there is no need to replace the panel.
Multiple LED strings go out; cannot attain appropriate intensity	Damaged LED light panel	Replace LED light panel
Light does not hold position	Arm tight	Check bolts, loosen as necessary
	Arm loose	Check bolts, tighten as necessary
	Light drifts	Gooseneck has memory that may prevent it from holding certain positions. Reposition gooseneck or use the arm to achieve desired location. Optimal position for the arm is parallel to the light height.

6. Routine Cleaning and Maintenance

6.1 Checking the Light Intensity

It is recommended that the intensity of the light be checked per hospital protocol or at least every six months.

Have a qualified technician test the intensity level and readjust the intensity potentiometer to achieve the desired output, if required

***Caution**: Only qualified personnel should perform service and repair. Use extreme care when working with exposed circuitry.*

6.2 Adjusting the Light Intensity

If the intensity of light falls to less than 30 µW/cm^2/nm, the light may be readjusted to increase its intensity. Refer to the neoBLUE mini device Service Manual for more information.

***Note:** The light will continue to operate with minimal degradation over time. Timing of potentiometer adjustments is per hospital protocol.*

***Note**: The light has been calibrated with the Ohmeda BiliBlanket® Meter II to deliver a peak intensity of 30-35 µW/cm^2/nm at a 12 inch (30.5 cm) distance from the baby. Please refer to section 9 of this manual or Tech Note, PN 051124 for information on other meters.*

6.3 Cleaning

⚠ ***Warning!** Disconnect light from AC power before cleaning.*

Remove dust from the exterior of the light with a soft brush or soft cloth dampened with water. Sponge away remaining debris with a mild solution of detergent and water, a noncaustic commercial cleaner, or hospital disinfectant.

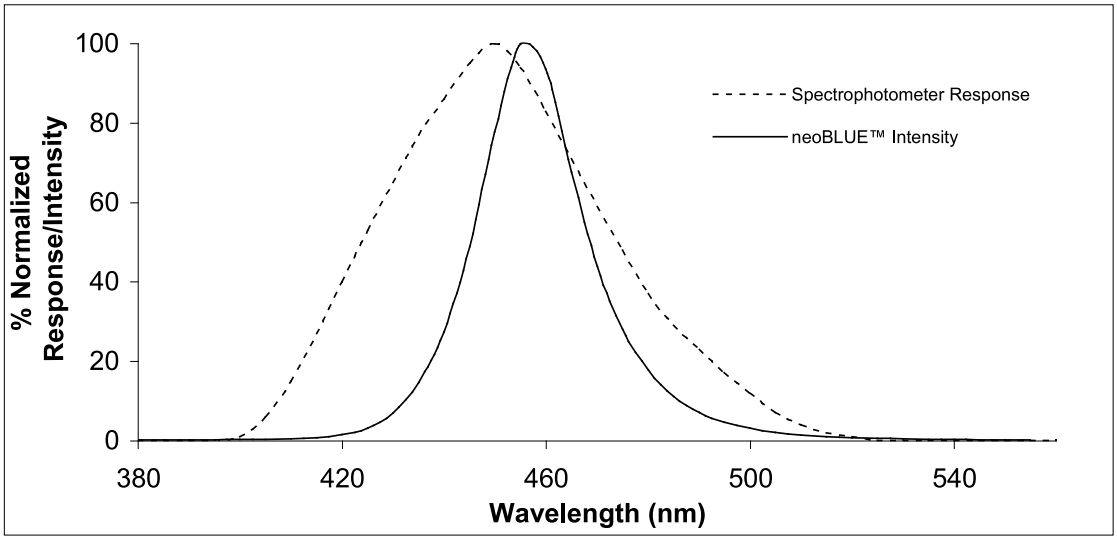
Clean the lens with a soft cloth dampened with water. If water alone is ineffective in removing fingerprints or other markings, use a mild solution of detergent and water, a noncaustic commercial cleaner, or hospital disinfectant.

***Caution:** Observe the following precautions:*

- *Do not spray liquids directly onto the light, or allow them to seep into the interior.*
- *Do not use caustic or abrasive cleaners.*
- *Do not clean with alcohol, acetone, or other solvents.*
- *Never immerse the light or its component parts.*

7. Technical Reference

The following graph shows the normalized spectra of the blue LEDs and the spectral sensitivity of the spectrophotometer.



Measurements for this light were made using a standard spectrophotometer.

The intensity of the light is set at the factory to 30-35 µW/cm^2/nm at a 12 inch (30.5 cm) distance from the light enclosure. This measurement is taken at the central area of the effective surface area for phototherapy.

The following table shows the approximate intensity in the center of the effective surface area with respect to distance from the light enclosure.

Distance in Inches (cm)	Intensity (µW/cm^2/nm)
8 in (20.3 cm)	40
12 in (30.5 cm)	35
18 in (45.7 cm)	25

8. Specifications

Light Source	Blue and Yellow LEDs
Wavelength	Blue: Peak between 450 and 470 nm Yellow: Peak between 585 and 595 nm
Intensity	Peak central intensity at 12 inches (30.5 cm) 30-35 µW/cm^2/nm
Variation in intensity over 6 hrs	< ± 10% (within illumination area)
Effective surface area at 12 in (30cm)	40 Square inches (258.1 cm²) Approximately 8 x 5 in (20.3 cm x 12.7 cm)
Intensity ratio	> 0.4 (minimum to maximum)
Heat output (at 12 in over 6 hrs) (at 30.5 cm over 6 hrs)	< 18° F (10° C) warmer than ambient
Electrical Mains	85–264 VAC, 47 to 63 Hz
Maximum Rating	0.7A, 100-240V~, 50/60 Hz
Safety	
Leakage current	< 100 µA
Audible Noise	< 60 dB
Dimensions	
Light	7.5 x 5.5 x 2 inches (19 x 14 x 5 cm) +/- 10%
Light with Arm	< 6 lbs (< 2.7 kg)
Arm	
Length	Extends to >32 inches (>81cm) The arm is designed to attach to poles with 0.75 to 1.5 inch (1.91 to 3.81 cm) diameters
Environmental	
Operating Temperature/Humidity	59° F to 95° F (15 to 35° C) / 0% to 90% non condensing
Storage Temperature/Humidity	-22° F to 122° F (-30 to 50° C) / 0% to 90% non condensing
Regulatory Standards	
	Type BF EN 60601-1-1, EN60601-1-2 EN60601-2-50 UL2601-1 CSA C22.2 606.1

9. Measuring the neoBLUE mini Light with a Photometer

This section provides important information about using photometers to measure the light intensity output of the neoBLUE® mini LED Phototherapy device.

Natus recommends that the neoBLUE mini light intensity output be checked with a photometer per hospital protocol or at least every six months. In addition, your photometer should be calibrated according to the manufacturer's specifications (typically on an annual basis). Checking intensity before each use will confirm the "dosage" of light being delivered. In addition, by checking the intensity at the center of the infant and at the infant's head and feet, you can confirm proper placement of the light.

The intensity of the light source is inversely related to the distance from the source. The neoBLUE mini LED Phototherapy System can be placed closer to the infant yielding a higher intensity or higher dosage treatment. To adjust the neoBLUE mini light to the desired intensity when changing the distance, please refer to the service manual.

The light intensity output of the neoBLUE mini device is measured at Natus prior to shipment with the Ohmeda BiliBlanket® Meter II. Because your facility may use a different photometer to measure the light intensity output, it is necessary to understand how your reading correlates to the Ohmeda reading. The following table provides a light intensity output conversion chart, when measured at 12 inches (30 cm) from the center of the neoBLUE mini light enclosure.

neoBLUE mini Light Intensity Output Conversion Chart

Photometer:	**Ohmeda BiliBlanket® Meter II**	**Joey Dosimeter Model JD100**	**Olympic Bili-Meter™**
Intensity: ($\mu W/cm^2/nm$)	35	90.6	20.6
	30	77.6	17.6
	25	64.5	14.2
	20	51.2	10.9
	15	38.0	7.8
	10	25.5	4.9
Reading Tolerance as per manufacturer:	+/- 3 %	+/- 2 %	+/-1.9 %

If needed, please call Natus Medical Technical Service at +1 888-496-2887 (US only) or your authorized service representative.